Evaluation of the Indiana Medicaid Preferred Drug List (PDL) Program

FINAL *Report #6*

PERIOD EVALUATED: 04-1-06 to 9-30-06

Presented by:
ACS Government Healthcare Solutions

For
State of Indiana
Office of Medicaid Policy and Planning
And
Indiana Medicaid DUR Board

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FOREWORD

Since the implementation of the Indiana Medicaid Preferred Drug List (PDL) in August of 2002, ACS has been pleased to both support the PDL and provide to the DUR Board the draft of a statutorily required, twice-annual PDL Report from the Board to the Select Joint Commission on Medicaid Oversight. Given the amount of time that has lapsed since the inception of the PDL, we believe it advisable to revise the format of this, the 6th PDL Report. We do so in an effort to emphasize and bring into sharper focus significant findings from prior reports, and to make it easier for the reader -- be it Board members who review and approve the report, legislative staff to whom it is directed, or members of the public -- to discern the most salient points from the current reporting period (in this instance, the time period of April 1, 2006 through September 30, 2006) as well as from prior periods (beginning July 1, 2002 through March 31, 2006).

In the past, much historical information has been carried forth from report to report. In an attempt to condense the size of this and future twice-annual reports, we have synthesized this information into a "Historical Summary" section that will list the notable findings from each iteration of the PDL Report, and will be included at the back of this and future reports. The Historical Summary section will be updated as time progresses and additional reports are issued. Detailed information that was included in prior reports that is not carried forth into the Historical Summary (again, for the purpose of conciseness) remains publicly available via copies of prior reports that are website-accessible (see www.indianamedicaid.com/ihcp/PharmacyServices/hcfa_dur_reports.asp, or www.indianapbm.com).

Other format enhancements include listing at the beginning of each report the "Key Findings" from prior reports and the current one, and a notation as to whether or not those findings have changed as a result of the analysis of the current reporting period. "Recommendations" is an important section of the report, since it contains suggestions as to how to improve the PDL itself, the PDL process, and/or the clinical and fiscal return to the State of both. "Analysis of the Current Reporting Period" will provide detailed information pertaining to the time frame being examined in the report.

We hope all readers find these report revisions and enhancements helpful in gaining a better understanding of the Indiana Medicaid Preferred Drug List and the substantial clinical and financial benefit that it provides to the program and those whom the program serves.

--ACS Government Healthcare Solutions
April 2007

OBJECTIVES

The goal of this and prior reports is to evaluate the overall impact of the Indiana PDL program upon costs (prescription and medical) and access to care for Indiana recipients.

Specifically, the four objectives in accordance with Indiana Code 12-15-35-28(h) are to evaluate:

1.) **Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.**

2.) **The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.**

3.) **The number of times prior authorization was requested, and the number of times prior authorization was: (A) approved and (B) disapproved.**

4.) **The cost of administering the preferred drug list.**

KEY FINDINGS

The key findings resulting from analyses of the impact of the Indiana PDL program conducted for the prior and current reports are listed as follows.

1. **Estimated PDL Program Savings**

The estimated savings from PDL program implementation in 2002 to present are:

- **Program savings before administrative costs are deducted:**
  Estimated savings to the program from the PDL program (after Federal rebates are considered) before administrative costs are deducted are approximately **$26.03 million**. Supplemental rebate savings after 4 years of operation are approximately **$24.37 million** and is in addition to savings obtained through the regular PDL program for a total savings of approximately $50.40 million.

- **Approximate administrative costs:**
  The costs to administer the PDL program over the 4-year period are approximately **$4.73 million.**

- **Net estimated savings:**
  Total estimated net savings after deducting administrative costs are approximately **$45.67 million** since the PDL program's inception.[1]

2. **No Significant Barriers to Prescription Medications**

All analyses have shown that the PDL program has not created any significant barriers to medically necessary medications. Since the first analysis report, there has been no evidence found to suggest that access to care is being compromised or that quality of care for recipients has suffered as a result of the PDL program. In fact, adherence to the prescribed drug regimen was demonstrated to be the more significant issue, not whether recipients were taking a preferred or non-preferred medication.

[1] NOTE: All dollars mentioned throughout the report are state and federal funds unless specifically stated otherwise.

3. **Medical Expenditures are Not Significantly Different**

All analyses have shown that the PDL program has not resulted in any statistically significant differences in overall medical expenditures for recipients impacted by the PDL as compared to recipients not impacted by the PDL.

4. **Behavioral Health Drug[2] Expenditures**

Behavioral health drugs have constituted over 30% of Indiana Medicaid prescription drug expenditures since 2003, and represent approximately **40%** of such expenditures for the time period of this (the 6th) report.

The Mental Health Quality Advisory Committee (MHQAC) has been tasked with developing guidelines and programs that promote appropriate use of mental health medications. The first approved edits were implemented on January 1, 2007.

5. **Additional Supplemental Rebates Could Be Realized If Behavioral Health Drugs Were Subjected to the PDL Process**

A preliminary estimate by ACS of additional supplemental rebates that could be gained were behavioral health drugs to be reviewed for PDL status, same as other drug classes comprising the PDL, revealed a figure of about **$9.2 million** (state and federal dollars) per year. Additional savings would likely accrue due to less net cost of those products that achieved preferred status.

KEY OBSERVATION of PDL SAVINGS SUMMARY:

Over the entire 4-year PDL program, the overall pharmacy savings is estimated to be $26.03 million plus an additional $24.37 million in estimated supplemental rebates for a total $50.40 million. Administrative costs are $4.73 million for a total net estimated savings of $45.67 million.

[2] "Behavioral Health Drugs," for purposes of this report, is synonymous with "mental health drugs." Both terms refer to antidepressants, antipsychotics, anti-anxiety drugs, and so called "cross-indicated drugs." Antidepressants, antipsychotics, anti-anxiety, and "cross-indicated drugs" are collectively referred to as "3A/X-indicated drugs."

Summary of Key Findings

A summary of key findings that have not changed since the first report to the current (6th) report is as follows:

1. The PDL program has saved money in each reporting period and overall. The addition of supplemental rebates to the PDL program has saved the state of Indiana and its taxpayers' money.

2. Once Indiana recipients changed from non-preferred to less costly, clinically-equivalent preferred drugs, the majority did not switch back to non-preferred up to 4 years later.

3. The PDL program has not created any significant barriers to medically necessary medications. No evidence has been found to suggest that access to care is being compromised or that quality of care for recipients has suffered as a result of the PDL program.

4. Behavioral health drugs have constituted over 30% of Indiana Medicaid prescription drug expenditures since 2003, and behavioral health drugs represent approximately 40% of such expenditures for the time period of this (6th) study. A preliminary estimate by ACS of additional supplemental rebates that could be gained were behavioral health drugs to be reviewed for PDL status, same as other drug classes comprising the PDL, revealed a figure of about **$9.2 million** (state and federal dollars) per year.

RECOMMENDATIONS

Over time, this report has included recommendations for improving the PDL and its associated processes in order to maximize the clinical and fiscal benefits that the PDL provides. Recommendations from prior reports have been reviewed in the context of the results of the analysis of the current reporting period (see page 11 for details pertaining to that analysis), and current recommendations are as follows:

1. Action could be taken by the General Assembly to allow for inclusion of behavioral health drugs in the PDL review process. By statute, all behavioral health drugs are currently considered as "preferred".

2. Criteria used in prior authorization determinations shall be reviewed to determine where such criteria could and should be made more rigorous in ensuring clinically and fiscally responsible drug therapy.

3. Consideration should be given to limiting the number of preferred drugs in any given therapeutic class, so as to increase possible savings to the Medicaid program. The amount of savings is directly related to the ability to increase the market share of the more favorably-priced medication(s) within a therapeutic class where medications are clinically equivalent. The more preferred products available within a therapeutic class, the less opportunity to move market share to the least expensive, clinically equivalent medication, and therefore less potential for savings.

4. ACS has reviewed specific areas of the PDL performance as well as general utilization trends. As a result, ACS recommends that the following therapeutic classes be reviewed for inclusion on the PDL. A potential fiscal impact (expressed as state and federal dollars combined) is included for each.

Hepatitis C Treatment Agents

Analysis. The course of treatment for patients with hepatitis C depends primarily on disease severity. For moderate or severe disease, the standard was previously a combination of interferon and ribavirin. New pegylated forms of inferferon are now considered treatment standards since they offer a longer-acting alternative to interferon, requiring weekly injections rather than an injection three times a week.

Potential Fiscal Impact. ACS has successfully added the Hepatitis C agents into the PDL review process for another client. The estimated

savings of adding the Hepatitis C agents to the PDL review process is approximately $390,000 per year.

Multiple Sclerosis Agents

Analysis. Multiple sclerosis, a chronic and recurrent disease of the central nervous system, is treated with anti-inflammatory, immunomodulatory, and immunosuppressive agents which are collectively referred to as disease-modifying treatments. In recent years, multiple agents have become available, some of which may offer substantial benefits over other options. In addition, this therapeutic class ranks twelfth among the top 100 therapeutic classes by total amount paid and eighth when considering only therapeutic classes not covered on the PDL.

Potential Fiscal Impact. ACS has successfully added the Multiple Sclerosis agents into the PDL review process for another client. The estimated savings of adding the Multiple Sclerosis agents to the PDL review process is approximately $60,000 per year.

Phosphate Binders

Analysis. Phosphate binders are indicated in patients with end-stage renal disease to reduce serum phosphate concentrations. Calcium carbonate (various), calcium acetate (PhosLo®), sevelamer (Renagel®), and lanthanum (Fosrenol®) are available options. Unlike the calcium salts, sevelamer and lanthanum can be given without affecting systemic calcium concentrations, which could be a concern in this patient population. However, these agents are associated with a significant increase in cost compared to calcium salts.

Potential Fiscal Impact. ACS has successfully added the Phosphate Binders into the PDL review process for another client. Assuming a 70% compliance rate, the estimated savings of adding the Phosphate Binders to the PDL review process is approximately $30,000 per year.

Topical Immunomodulators

Analysis. The topical immunomodulators, tacrolimus (Protopic®) and pimecrolimus (Elidel®), are indicated for atopic dermatitis in patients who are intolerant or unresponsive to first-line options. By incorporating this therapeutic class into the PDL, the State would potentially benefit from manufacturer rebates for the preferred agent.

Potential Fiscal Impact. ACS has successfully added the Topical Immunomodulators into the PDL review process for another client. The

estimated savings of adding the Topical Immunomodulators to the PDL review process is approximately $6,000 per year.

Ulcerative Colitis

Analysis. Treatment of ulcerative colitis consists of oral systemic therapy as well as topical treatments depending on the extent of disease. Patients with distal inflammation may be treated with topical therapy; whereas, patients with extensive disease require systemic medication.

Potential Fiscal Impact. Assuming a 70% compliance rate, the estimated savings of adding the Ulcerative Colitis agents to the PDL review process is approximately $21,000 per year. [3]

[3] The DUR Board voted that all classes recommended above be reviewed by the P & T Committee for possible inclusion in the Preferred Drug List program.

ANALYSIS OF THE CURRENT REPORTING PERIOD

This report contains evaluation of Indiana PDL program operations during the most current reporting period -- dates of service from April 1, 2006 to September 30, 2006. This evaluation, Report #6, involved 65 therapeutic classes in the second half of Year 4 (from approximately 3 ½ to 4 years into PDL program operations, or from 44 to 49 months) after PDL program operations first began. This section of Report #6 is organized by major topics contained in the original legislative requirements similar to the format in the "Key Findings" section.

1. Estimated PDL Program Savings

Total estimated savings (after Federal rebates are considered) were approximately $1.96 million. Associated supplemental rebate savings were approximately $2.89 million. The combined PDL program and supplemental rebate savings total was approximately **$4.85 million** for the six-month reporting period. The costs to administer the PDL program are approximately $675,000 for the six-month reporting period. The **net estimated combined PDL program and supplemental rebate savings** after deducting administrative costs for the PDL program were approximately **$4.18 million** for this reporting period. The net estimated savings for the PDL program alone after deducting administrative costs were $1.29 million.

Preferred Drug Market Share Shifts

Overall, the preferred drug market share shifted from 75.2% before implementation to 95.8% after Year 1, and has remained steady at approximately **95.8% preferred** throughout, up to this report, the 2nd half of Year 4. In general, once recipients are switched to preferred drugs, they tend to remain on preferred drugs.

Estimated Net Savings Estimates: All Reports 8/1/02 to 4/1/06

Table 1 on the next page depicts the total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) for each time period evaluated and over the entire 4-year period.

Table 1. Number of Classes, Rebate Shifts & Estimated Savings[4]

Time Period	# Classes Affected by the PDL Program	Total Estimated Savings from Market Share Shifts[5] before Rebates	Total Estimated Rebate Shifts	Total Net Savings[6] Estimates Minus Federal Rebate Estimates	Estimated Cost of Administering the PDL	Total Net Savings[7] Estimates Minus Rebates & Estimated Cost of Administering the PDL
Year 1 (8/1/02 to 7/31/03)	52	$12.43 million	- $3.52 million	$8.91 million	-$1.13 million	$7.78 million
Year 2 (10/1/03 to 9/30/04)	54	$2.06 million	- $0.93 million	$1.13 million	-$1.13 million	$175,000
1st half Year 3 (10/1/04 to 3/31/05)	62	$1.99 million	- $0.13 million	$1.86 million	-$562,500	$1.30 million
2nd half Year 3 (4/1/05 to 9/30/05)	67	$10.96 million	- $1.73 million	$9.23 million	-$562,500	$8.67 million †
1st half Year 4 (10/1/05 to 3/31/06)	64	$4.53 million	-$1.59 million	$2.94 million	-$675,000	$2.27 million
2nd half Year 4 (4/1/06 to 9/30/06)	65	$2.92 million	- $0.96 million	$1.96 million	-$675,000	$1.29 million
SubTotal	--	$34.86 million	- $8.86 million	**$26.03 million**	**-$4.73 million**	$21.30 million
Supplemental Rebate Savings (10/1/04 to 3/31/05)				**$6.08 million***	**+ $24.37 Million**	
Supplemental Rebate Savings (4/1/05 to 9/30/05)				**$7.81 million**		
Supplemental Rebate Savings (10/1/05 to 3/31/06)				**$7.59 million**		
Supplemental Rebate Savings (4/1/06 to 9/30/06)				**$2.89 million**		
GRAND TOTAL Net Savings (for 4 years since implementation) →					**$45.67 Million**	

[4] All savings and net savings are estimated.
[5] Estimates include both state and federal share.
[6] Estimates include both state and federal share.
[7] Estimates include both state and federal share.
* Report #3 reported supplemental rebate savings for the Oct-04 to Mar-05 period as $6.81 million. After all adjustments were made, the supplemental rebate savings changed to $6.08 million; therefore, supplemental rebate savings were adjusted accordingly in Report #4 and all reports going forward.

Report Period Six - 04/1/06 to 9/30/06: Partitions of Drug Expenditures

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 04/1/06 to 9/30/06 was an estimated $145.2[8] million (Chart 1). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (7.4%) = $10.75 M
- PDL classes with limited[9] benefit @ >95% preferred prior to implementation (23.0%) = $33.38 M
- AAAX[10] (considered preferred per statute) (39.8%) = $57.86 M
- Classes Not Reviewed[11] (29.8%[12]) = $43.27 M

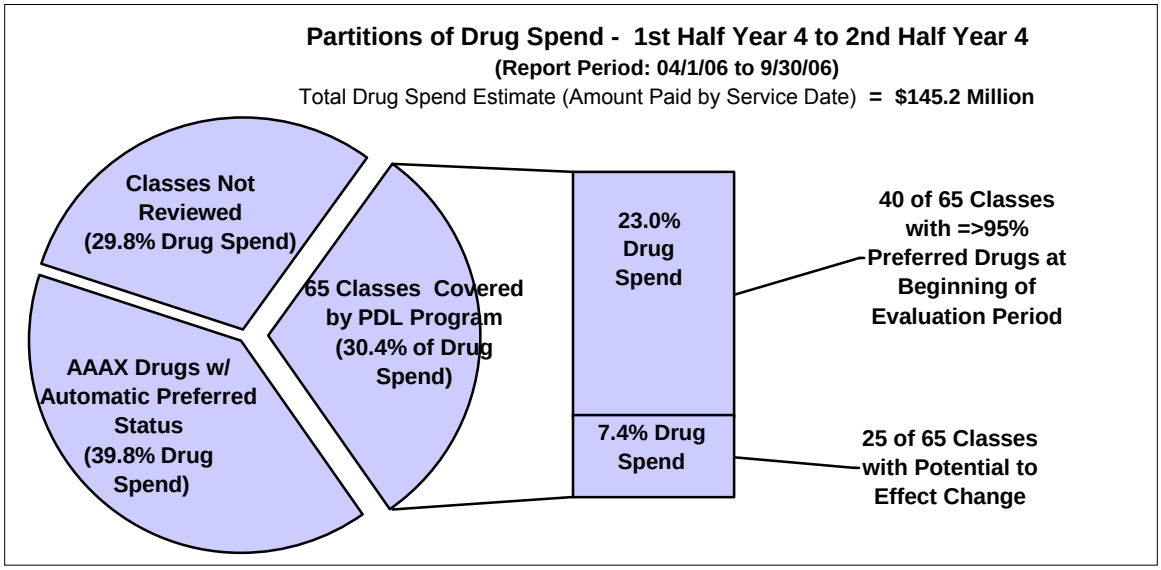

Chart 1. Partitions of Total Drug Expenditures ($145.2 Million): 4/1/06 to 9/30/06
Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be **an additional $2.27 million for the second half of Year 4 (April to September 2006) with 65 PDL classes.**

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[8] Estimates are from 04/1/06 to 9/30/06 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees). Also note there was expenditure shifting due to Medicare Part D drug program implementation that began on 1/1/06.

[9] Over 95% of market share were preferred drugs at the beginning of the second half of Year 4.

[10] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

[11] Drug classes of medications not on the PDL program from April 2006 to September 2006.

[12] Expenditures for classes not reviewed increased as a percentage of total spending from the 1st half of Year 4 to the 2nd half of Year 4 because more new drugs with high prices came onto market that had not yet been reviewed, and the proportion of drugs that were covered by the PDL program shrank after Medicare D implementation.

2. **Behavioral Health Drug[13] Expenditures**

Behavioral health drugs have constituted over 30% of Indiana Medicaid prescription drug expenditures since 2003, and behavioral health drugs represent approximately **40%** of such expenditures for the time period of this (6th) study.

The Mental Health Quality Advisory Committee (MHQAC) has been tasked with developing guidelines and programs that promote appropriate use of mental health medications. The first approved edits were implemented on January 1, 2007.

3. **Additional Supplemental Rebates Could Be Realized If Behavioral Health Drugs Were Subjected to the PDL Process**

A preliminary estimate by ACS of additional supplemental rebates that could be gained were behavioral health drugs to be reviewed for PDL status, same as other drug classes comprising the PDL, revealed a figure of about **$9.2 million** (state and federal dollars) per year. Additional savings would likely accrue due to less net cost of those products that achieved preferred status.

Based upon 4-years of PDL program evaluation results, if behavioral health drugs were to be reviewed by the P&T committee for clinical efficacy and therapeutic appropriateness, just as other drug classes are reviewed in the PDL, then there is no evidence to suggest that recipients would have problems with access to clinically appropriate drug therapy, or that medical costs or number of medical visits would significantly change. In addition, the General Assembly should not ignore the momentous savings that could be achieved if the other 40% of the prescription drug budget constituting behavioral health drugs were allowed to undergo non-biased, clinical review through the PDL process so that recipients could receive clinically- appropriate drugs while minimizing the cost incurred by the taxpayers who fund this benefit.

[13] "Behavioral Health Drugs," for purposes of this report, is synonymous with "mental health drugs." Both terms refer to antidepressants, antipsychotics, anti-anxiety drugs, and so called "cross-indicated drugs." Antidepressants, antipsychotics, anti-anxiety, and "cross-indicated drugs" are collectively referred to as "3A/X-indicated drugs."

4. **No Significant Barriers to Prescription Medications**

All analyses have shown that the PDL program has not created any significant barriers to medically necessary medications. Since the beginning of the first analysis report, there has been no evidence found to suggest that access to care is being compromised or that quality of care for recipients has suffered as a result of the PDL program. In fact, adherence was demonstrated to be the more significant issue, not whether recipients were taking a preferred or non-preferred medication.

PDL Report #6 Evaluation

Of the 107,783 monthly recipients followed for 6 months (April 2006 to September 2006), only 2,043 (1.8%) experienced a denied claim.

Report #6 evaluated Medicaid recipients' claims during the month of September 2006 for 16 therapeutic classes of maintenance medications. Of the 16 therapeutic classes in the month of September 2006, a total of 108,519 unique recipients had paid and denied claims, of which only 594 recipients (0.55%) experienced a denial. Thirty-six of the 594 recipients experienced a denied claim with no subsequent paid claim because they were no longer eligible. Of the 558 recipients still eligible, 0.51% experienced a denied claim. Over 95% of the recipients who had exceptions with subsequent paid claims were getting early fills of medication; therefore, if recipients received the medication within 30 days of the PDL exception, there should be no break or stoppage in taking therapy due to lack of access to medications. Of the recipients who experienced a PDL denial and who had a subsequent paid claim, 87% received a paid claim within 24-hours to 30 days of the denial; whereas, 13% of those with a denied claim or 0.05% of total recipients received a paid claim within 31 to 180 days of the denial.

The 52 (0.05%) recipients who experienced a denial with a subsequent paid claim 31 to 180 days later may have experienced a delay in taking medication. There is also the possibility that some of these recipients had samples or other medications at home and therefore didn't request the medication again until they needed it. Of the recipients who did not have a subsequent paid claim, it is impossible to determine how many may have gotten their medications through the Medicare D program and how many may no longer have needed the medication.

Overall, the initial number of recipients who may have experienced a delay in receiving needed medications (0.78% without a related claim within 30 days of the denial in the first year) suggests a minimum impact on PDL users. Further, denials diminished in later evaluation periods as providers gained experience with the PDL program as evidenced by the 0.023% at 26 months, 0.013% at 31 months, and 0.05% at 49 months after the program began.

Conclusions about Access to Care Results

- The proportion of users with a denied claim due to PDL program was low.
  In this analysis period, only 1.8% of recipients subject to the PDL experienced a denied claim.

- Recipient ineligibility explains why some exception events did not result in a prescription being filled for a medication in the class or a related class.
  Thirty-six of the 594 recipients who experienced a denied claim with no subsequent paid claim (6.1%) were no longer eligible.

- Delays in the receipt of medications were in part due to recipients seeking to refill their prescriptions too early.
  Many of the recipients who experienced a denial with subsequent paid claims were getting early fills of medication; therefore, if recipients received the medication within 23 to 30 days of the PDL exception, there should be no break in taking therapy due to lack of access to medications.

  Relatively few eligible recipients (0.05%) with an exception event had no claims for follow up medication in the same or a related class within 30 days of the event.

5. **Medical Costs are Not Significantly Different**

All analyses have shown that the PDL program has not resulted in any statistically significant differences in overall medical expenditures for those recipients impacted by the PDL as compared to those recipients not impacted by the PDL.

For Report #6, of the therapeutic classes evaluated, overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences (p-0.18, power=0.7) when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation, or already taking non-preferred prior to and after implementation). In other words, recipients affected by the PDL program were not associated with any statistically significant differences in overall medical expenditures when compared to recipients not affected by the PDL program measured at 49 months after PDL implementation. **This finding is consistent with prior Reports #1 through #5 in demonstrating that recipients affected by the PDL program were not associated with any statistically significant differences in overall medical expenditures when compared to recipients not affected by the PDL program measured at 12, 25, 31, 37, 43 and 49 months after PDL implementation.**

In sum, when examining **specific medical service types** at 12, 25, 31, 37, 43, and 49 months after PDL implementation of a therapeutic class, there is no evidence to suggest that specific medical costs (e.g. other health care providers, lab, emergency room services or hospital services) are higher on a wide, systematic scale for recipients switched to

taking preferred drugs or already taking preferred drugs versus recipients taking non-preferred drugs.

Additionally, of the therapeutic classes evaluated, **overall medical expenditures** of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation). It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned to take preferred or non-preferred drugs; therefore, only association or lack of association can be determined. Sample sizes were measured in number of recipients.

6. Preferred Drug List Program Prior Authorizations

Table 2. Preferred Drug List Prior Authorizations (PDL PA) Summary

Time Period	Average # Utilizers per Month	Total All PA's Requested	Approved	*% Approved*	# Approved PUPM*	Denied	*% Denied*	# Suspended	*% uspended*
2nd 6 months – FFY2006 (4-1-06 to 9-30-06) 2nd Half of Year 4 – Report #6	107,783	14,410	14,186	*98.4%*	0.0219	213	*1.5%*	11	*0.1%*
First 6 months - FFY06 (10-1-05 to 3-31-06) 1ST Half of Year 4 – Report #5	129,790	19,073	18,978	*99.5%*	0.0244	77	*0.4%*	18	*0.1%*

* Per utilizer per month (PUPM)

Table 3. Number of PDL PAs by Therapeutic Class

PAs from PDL Program from Apr 1, 2006 to Sep 30, 2006			
PDL PA Totals by Therapeutic Class	**Approved**	**Denied**	**Suspended**
ACE Inhibitors	23	1	0
ACEI with CCB	37	0	0
ACEI with Diuretics	3	0	0
Acne Agents	9	0	0
Actiq	0	0	0
Agents to treat COPD	80	0	0
Alpha Adrenergic Blockers	45	1	0
Angiotensin Receptor Blockers (ARBs)	206	0	0
Antidiabetic Agents	207	3	0
Antiemetic - Antivertigo Agents	83	1	0
Antifungal Oral	70	4	0
Antifungal Topical	71	3	0
Antipsoriatics	14	0	0
Anti-Ulcer - H Pyloric Agents	25	0	1
Antiviral Anti-herpetic Agent	65	0	0
Antiviral Influenza Agents	55	0	0
ARBs with Diuretics	74	0	1

Benign Prostatic Hypertrophy	47	1	0
Beta and Alpha/Beta Blockers	108	0	0
Beta Adrenergics and Corticosteroids	157	2	0
Bile Acid Sequestrants	105	0	0
Brand NSAIDS	156	35	0
Calcium Channel Blockers	67	2	0
Calcium Channel Blockers w/HMG CoA Reductase	48	1	0
Cephalosporins	25	5	0
Cox-2 Inhibitor	231	13	0
Eye Antibiotic- Corticosteroid Combo	5,619	23	2
Eye Antihistamines	0	0	0
Fibric Acids	94	1	0
Fluoroquinolones	88	2	0
Forteo	28	2	0
H2 Antagonists	72	5	0
Hematinics	39	0	0
Heparin and Related Products	2	1	0
HMG CoA Reductase Inhibitors	2	0	0
Inhaled Glucocorticoids	149	2	1
Inspra	7	0	0
Ketolides	12	0	0
Leukocyte Stimulants	12	0	0
Leukotriene Receptor Antagonists	174	2	1
Long Acting Beta Agonists	13	0	0
Loop Diuretics	0	0	0
Macrolides	47	0	0
Miotics- OIPR	58	1	0
Narcotics	1,048	24	2
Nasal Steroids and Antihistamines	135	1	0
Non-Sedating Antihistamines	896	7	2
Ophthalmic Antibiotics	31	1	0
Opthalmic Mast Cell Stabilizers	2	0	0
Otic Antibiotics	60	1	0
Other Lipotropics	79	0	0
Platelet Aggregation Inhibitors	4	0	0
Proton Pump Inhibitors	2,246	29	1
PPI/NSAID Combination	8	0	0
SERMS - Bone Resorption Agents	73	2	0
Short Acting Beta Agonists	202	2	0
Skeletal Muscle Relaxants	305	6	0
Smoking Deterrent Agents	3	0	0
Stadol	0	0	0
Systemic Vitamin A Deriv.	2	0	0
Thiazolidenediones	78	0	0
Topical Estrogen Agents	3	1	0
Topical Vitamin A Deriv.	53	0	0
Triptans	66	1	0
Urinary Tract Antispasmodics - Antiincontinence	220	5	0
Vaginal Antimicrobials	92	0	0
Wound Care	153	22	0
PDL PA TOTALS - Apr to Sep06	**14,186**	**213**	**11**

HISTORICAL SUMMARY

This section gives a short history of the PDL program's genesis and a short history of what prior reports (Reports 1 – 5) have shown – individually and collectively.

In the past, much historical information has been carried forth from report to report. In an attempt to condense the size of this and future twice-annual reports, we have synthesized this information into this "Historical Summary" section that lists the notable findings from each iteration of the PDL Report. This Historical Summary section will be updated as time progresses and additional reports are issued. Detailed information that was included in prior reports that is not carried forth into the Historical Summary (again, for the purpose of conciseness) remains publicly available via copies of prior reports that are website-accessible (see www.indianapbm.com, or www.indianamedicaid.com/ihcp/PharmacyServices/hcfa_dur_reports.asp). Please refer to the web site if you would like to read an earlier report in its entirety.

The Historical Summary section is organized into headings as follows:

1. **Preferred Drug Market Share**
2. **Estimated PDL Program Savings**
3. **Partitions of Prescription Drug Expenditures**
    a. **Behavioral Health Drug Expenditures**
    b. **Report Periods 1-6: Partitions of Drug Expenditures**
4. **PDL Program Prior Authorizations (PA) Totals**
5. **Access to Prescription Medications**
6. **Impact of the PDL Program Upon Medical Costs**

1. Preferred Drug Market Share

Overall, the **preferred drug market share** shifted from approximately **75.2% to 95.8%** during the Year 1 period, then shifted slightly back toward non-preferred drugs to approximately **93.8%** preferred at the end of Year 2. The preferred drug market share then increased to **98.7%** for the 1st half of Year 3, then decreased slightly back to **95.4%** preferred at the end of the second half of Year 3; and, remained steady at approximately **95.8%** preferred through the 1st and 2nd half of Year 4.

2. Estimated PDL Program Savings: All Reports 8/1/02 to 4/1/06

Table 4 depicts the total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) for each time period evaluated and over the entire 4-year period.

Table 4. Number of Classes, Rebate Shifts & Estimated Savings[14]

Time Period	# Classes Affected by the PDL Program	Total Estimated Savings from Market Share Shifts[15] before Rebates	Total Estimated Rebate Shifts	Total Net Savings[16] Estimates Minus Federal Rebate Estimates	Estimated Cost of Administering the PDL	Total Net Savings[17] Estimates Minus Rebates & Estimated Cost of Administering the PDL
Year 1 (8/1/02 to 7/31/03)	52	$12.43 million	- $3.52 million	$8.91 million	-$1.13 million	$7.78 million
Year 2 (10/1/03 to 9/30/04)	54	$2.06 million	- $0.93 million	$1.13 million	-$1.13 million	$175,000
1st half Year 3 (10/1/04 to 3/31/05)	62	$1.99 million	- $0.13 million	$1.86 million	-$562,500	$1.30 million
2nd half Year 3 (4/1/05 to 9/30/05)	67	$10.96 million	- $1.73 million	$9.23 million	-$562,500	$8.67 million †
1st half Year 4 (10/1/05 to 3/31/06)	64	$4.53 million	-$1.59 million	$2.94 million	-$675,000	$2.27 million
2nd half Year 4 (4/1/06 to 9/30/06)	65	$2.92 million	-$0.96 million	$1.96 million	-$675,000	$1.29 million
SubTotal	--	$34.86 million	- $8.86 million	**$26.03 million**	**-$4.73 million**	$21.30 million
Supplemental Rebate Savings (10/1/04 to 3/31/05)				**$6.08 million***		
Supplemental Rebate Savings (4/1/05 to 9/30/05)				**$7.81 million**		**+ $24.37 Million**
Supplemental Rebate Savings (10/1/05 to 3/31/06)				**$7.59 million**		
Supplemental Rebate Savings (4/1/06 to 9/30/06)				**$2.89 million**		
GRAND TOTAL Net Savings (for 4 years since implementation) →						**$45.67 Million**

† ***Reason for Increased Savings from 1st Half to 2nd Half of Year 3†***

The large increase in net savings from the first half of Year 3 to the 2nd half of Year 3 illustrated in Table 4 was attributable to two factors: 1.) Federal CMS rebate savings resulting from large changes in the PDL program; and, 2.) Savings resulting from less utilization due to implementation of step edits and quantity limits. Most of the savings

[14] All savings and net savings are estimated.
[15] Estimates include both state and federal share.
[16] Estimates include both state and federal share.
[17] Estimates include both state and federal share.
* Report #3 reported supplemental rebate savings as $6.81 million. After all adjustments were made, the supplemental rebate savings changed to $6.08 million; therefore, supplemental rebate savings were adjusted accordingly in Report #4.

came from a few classes. For example, the 'Brand Name Narcotics' therapeutic category jumped from 92.4% preferred to 99.3% preferred. Additionally generic oxycodone ER 80mg and fentanyl patches were placed on the preferred list while Palladone® was placed on the non-preferred list. Fentanyl was limited to 10 patches per 30 days, and a step edit was added to Palladone® (which was removed from market in mid-July). Step edits, quantity limits and shifting of agents on the PDL list resulted in a net savings of approximately $5.5 million in this one Narcotics therapeutic class alone.

A similar situation occurred with the gastrointestinal (GI) agents therapeutic class, 'Proton Pump Inhibitors (PPIs).' Omeprazole switched from prescription to an over-the-counter drug and a step therapy edit was implemented requiring new patients to try an H_2 blocker or OTC Prilosec® prior to receiving a preferred PPI. Prevacid® changed from PDL neutral to non-preferred; while a step therapy edit was implemented with a quantity limit of one capsule per day for Nexium®. Step edits, quantity limits and shifting of agents on the PDL list resulted in a net savings of approximately $3.5 million in the GI therapeutic category.

Finally, the 'Non-sedating Antihistamines' therapeutic class had several changes. Allegra® was switched to non-preferred; step edits were added so that patients must fail a trial of OTC loratadine before obtaining other non-sedating antihistamines whether preferred or non-preferred; and, quantity limits were implemented for the non-preferred drug Allegra®. Step edits, quantity limits and shifting of agents on the PDL list resulted in a net savings of approximately $1.4 million in Non-Sedating Antihistamine therapeutic class.

In sum, changes from preferred to non-preferred created shifts in net CMS rebates resulting in savings. Additionally, step therapy edits and quantity limits have resulted in substantial savings by less utilization of expensive drugs.

3. Partitions of Prescription Drug Expenditures

Behavioral Health Drug Expenditures

Behavioral health drugs have constituted over 30% of Indiana Medicaid prescription drug expenditures since 2003, and behavioral health drugs represent approximately **40%** of such expenditures for the time period of this (6^{th}) study.

The Mental Health Quality Advisory Committee (MHQAC) has been tasked with developing guidelines and programs that promote appropriate use of mental health medications. The first approved edits were implemented on January 1, 2007.

Report Period One: 8/1/02 to 7/31/03 - Partitions of Drug Expenditures

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 8/1/02 to 7/31/03 were an estimated $642[18] million (Chart 2). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (24%) = $154 M
- AAAX[19] (considered preferred per statute) (31.1%) = $200 M
- Classes Not Reviewed[20] (27%) = $173 M
- PDL classes with limited[21] benefit @ >95% preferred prior to implementation (18%) = $116 M

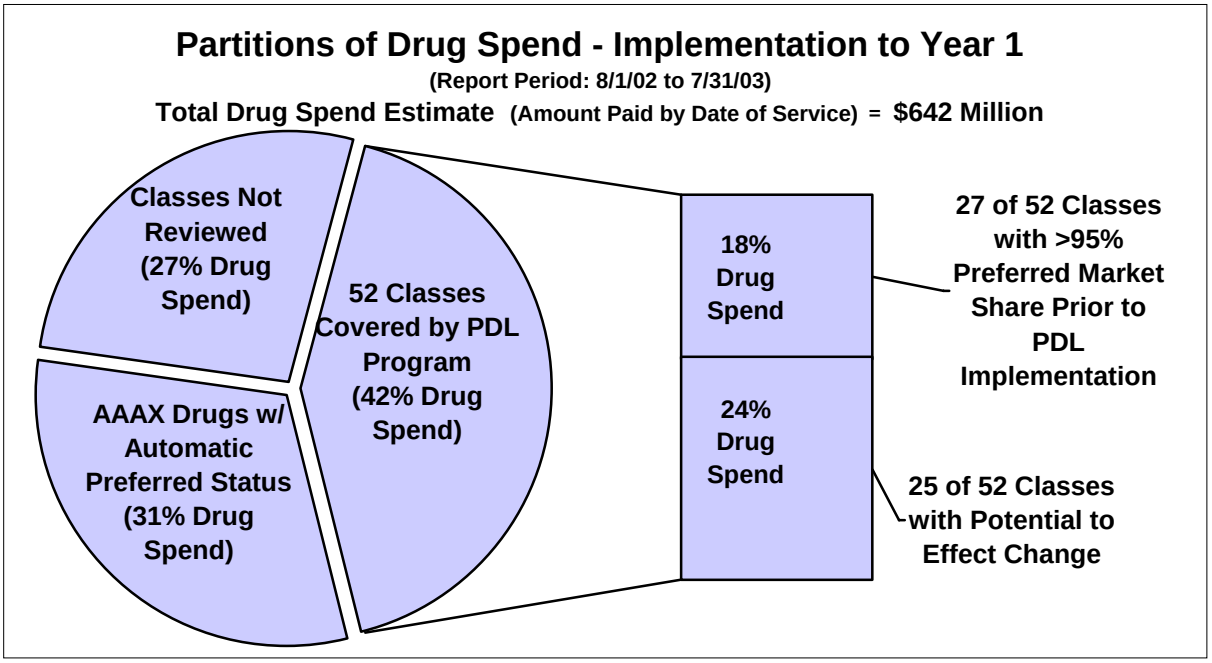

Chart 2. Partitions of Total Drug Expenditures ($642 Million) from 8/1/02 to 7/31/03
Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions after market share shifts and cost to administer the PDL program) in the **52 PDL classes implemented and evaluated from August 2002 to September 2003** (Year 1 post-PDL implementation) were estimated to be **$7.78 million**.

[18] Estimates are from 8/1/02 to 7/31/03 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).

[19] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

[20] Drug classes of medications not on the PDL program from August 2002 to August 2003.

[21] Over 95% of market share were preferred medications prior to implementation.

Report Period Two: 10/1/03 to 9/30/04 (FFY 2004) Partitions of Drug Expenditures

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/03 to 9/30/04 were an estimated $736[22] million (Chart 3). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (14%) = $103 M
- AAAX[23] (considered preferred per statute) (31.1%) = $229 M
- Classes Not Reviewed[24] (28.2%) = $208 M
- PDL classes with limited[25] benefit @ >95% preferred prior to implementation (26.6%) = $196 M

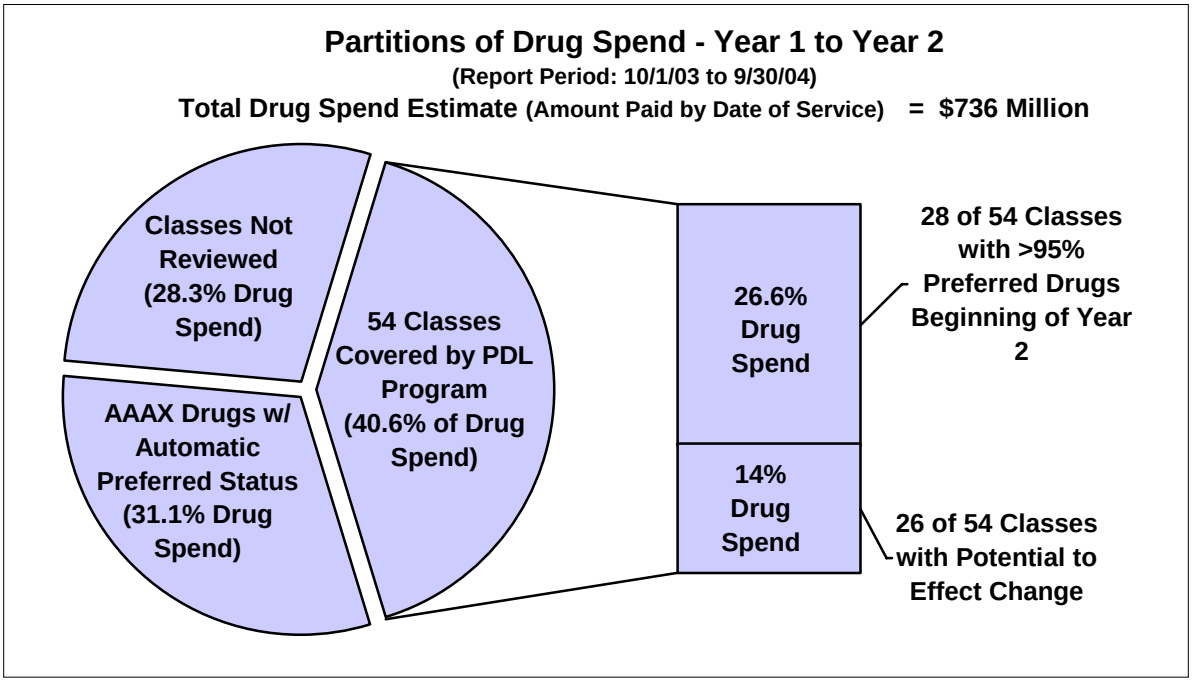

Chart 3. Partitions of Total Drug Expenditures ($736 Million) from 10/1/03 to 9/30/04
Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] rebate deductions and cost to administer the PDL program) due to market share shifts in the 54 PDL classes implemented and evaluated beginning in August 2002 are estimated to be **$7.78 million in Year 1**, and an **additional $175,000 in Year 2** with two additional classes added to the analysis.

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[22] Estimates are from 10/1/03 to 9/30/04 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).

[23] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

[24] Drug classes of medications not on the PDL program from October 2003 to September 2004.

[25] Over 95% of market share were preferred drugs at beginning of Year 2.

Report Period Three: 10/1/04 to 3/31/05 Partitions of Drug Expenditures

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/04 to 3/31/05 were an estimated $392[26] million (Chart 4). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (14.7%)= $57.4 M
- PDL classes with limited[27] benefit @ >95% preferred prior to implementation (22.3%) = $87.6 M
- AAAX[28] (considered preferred per statute) (30.4%) = $119 M
- Classes Not Reviewed[29] (32.6%[30]) = $128 M

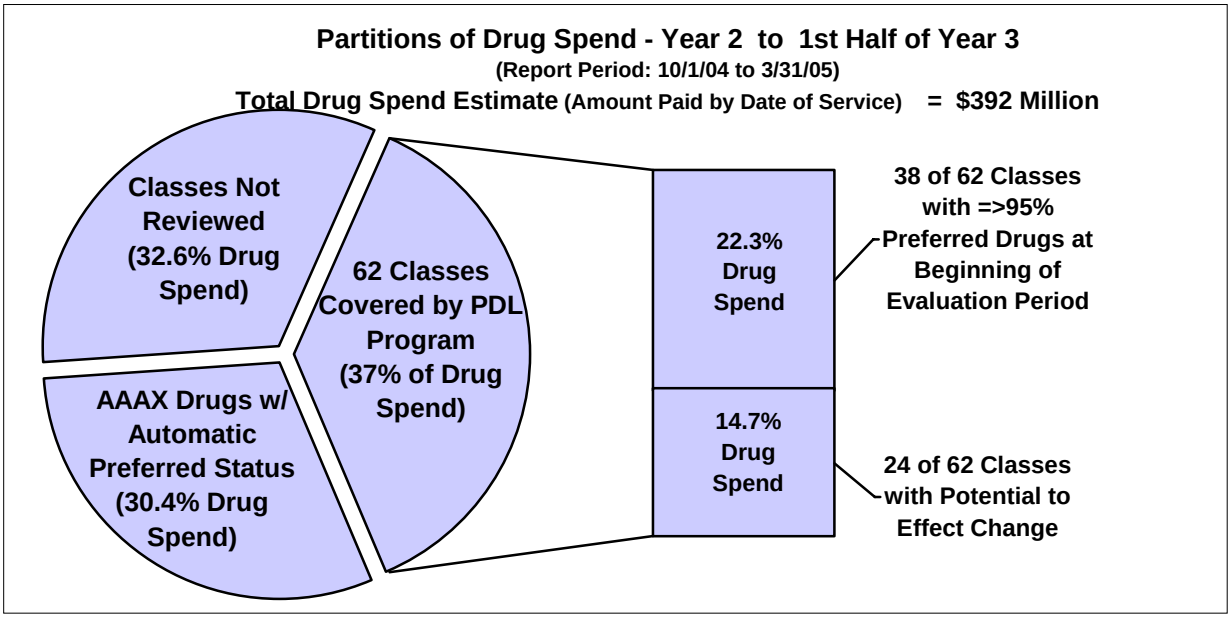

Chart 4. Partitions of Total Drug Expenditures ($392 Million) from 10/1/04 to 3/31/05
Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be **an additional $1.30 million for the first half of Year 3 (October 2004 through March 2005) with 62 PDL classes** (8 additional classes added to the analysis).

[26] Estimates are from 10/1/04 to 3/31/05 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees).
[27] Over 95% of market share were preferred drugs at the beginning of Year 3.
[28] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).
[29] Drug classes of medications not on the PDL program from October 2004 to March 2005.
[30] Expenditures for classes not reviewed grew as a percentage of total spending from Year 2 to the first half of Year 3 because many new drugs with high prices came onto market that had not yet been reviewed.

Report Period Four: 4/1/05 to 9/30/05 Partitions of Drug Expenditures

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 4/1/05 to 9/30/05 were an estimated $354.5[31] million (Chart 5). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (10.8%)= $38.1 M
- PDL classes with limited[32] benefit @ >95% preferred prior to implementation (25.4%) = $90.2 M
- AAAX[33] (considered preferred per statute) (30.6%) = $108 M
- Classes Not Reviewed[34] (33.2%[35]) = $117.7 M

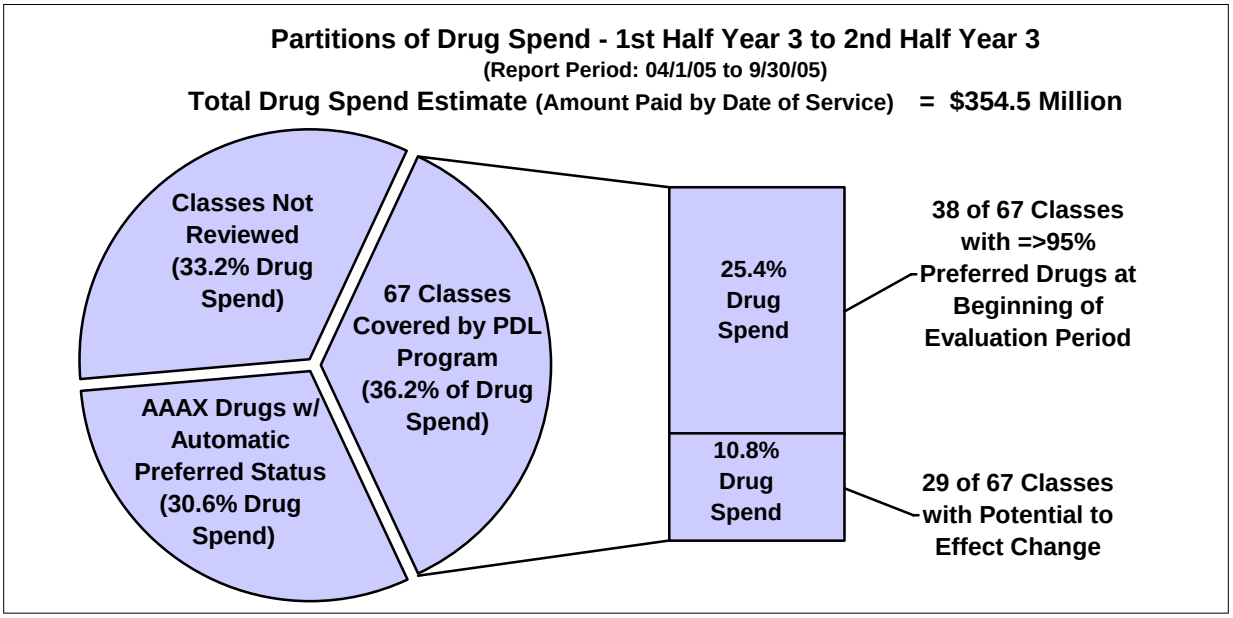

Chart 5. Partitions of Total Drug Expenditures ($354.5 Million) from 4/1/05 to 9/30/05
Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be **an additional $8.67 million for the second half of Year 3 (April 2005 through September 2005) with 67 PDL classes** (5 additional classes added to the analysis from Study 3 to 4).

[31] Estimates are from 04/1/05 to 9/30/05 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. . (Dollar amount includes drug ingredient costs plus dispensing fees).
[32] Over 95% of market share were preferred drugs at the beginning of the second half of Year 3.
[33] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).
[34] Drug classes of medications not on the PDL program from April 2005 to September 2005.
[35] Expenditures for classes not reviewed grew as a percentage of total spending from the first to second half of Year 3 because many new drugs with high prices came onto market that had not yet been reviewed.

Report Period Five: 10/1/05 to 3/31/06 Partitions of Drug Expenditures

The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual date of service period of 10/1/05 to 3/31/06 was an estimated $254.6[36] million (Chart 6). This figure includes four major categories partitioned by estimated paid amount:

- PDL Applicable – PDL Classes with Potential to Effect Change (9.4%) = $23.86 M
- PDL classes with limited[37] benefit @ >95% preferred prior to implementation (25.0%) = $63.8 M
- AAAX[38] (considered preferred per statute) (38.9%) = $99 M
- Classes Not Reviewed[39] (26.7%[40]) = $67.9 M

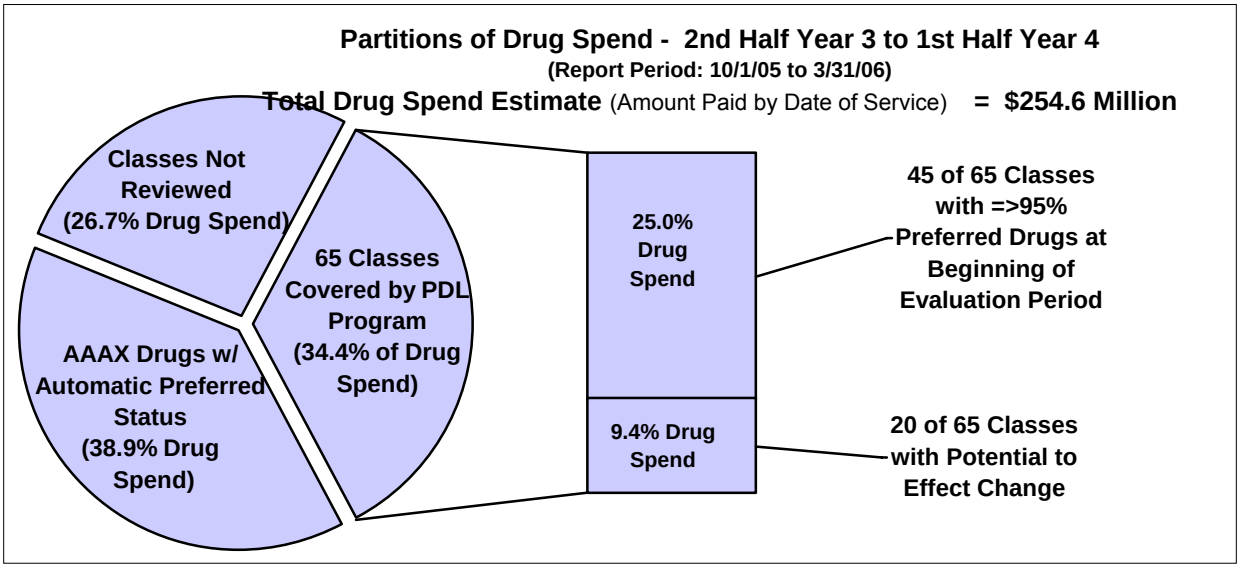

Chart 6. Partitions of Total Drug Expenditures ($254.6 Million) from 10/1/05 to 3/31/06
Source: ACS Government Healthcare Solutions Analysis of OMPP data.

Total annualized pharmacy benefit net savings (after CMS [standard Federal] deductions and cost to administer the PDL program) were estimated to be **an additional $2.27 million for the first half of Year 4 (October 2005 through March 2006) with 64 PDL classes** (3 classes no longer reviewed from Study 4 to 5).

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[36] Estimates are from 10/1/05 to 3/31/06 claims data by date of service and includes both state and federal share. It does not include rebates Indiana received from drug manufacturers as part of the Medicaid federal rebate program or state supplemental rebate program. (Dollar amount includes drug ingredient costs plus dispensing fees). Also note there was expenditure shifting due to Medicare Part D drug program implementation on 1/1/06.

[37] Over 95% of market share were preferred drugs at the beginning of the first half of Year 4.

[38] These medications are considered preferred per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs, such as: (1) central nervous system drugs, and (2) drugs prescribed for the treatment of a mental illness (as defined by the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders).

[39] Drug classes of medications not on the PDL program from October 2005 to March 2006.

[40] Expenditures for classes not reviewed decreased as a percentage of total spending from the 2nd half of Year 3 to the 1st half of Year 4 because less new drugs with high prices came onto market that had not yet been reviewed, and drugs that had come into the market in Years 2 & 3 had been reviewed.

4. Preferred Drug List Program Prior Authorizations

Preferred Drug List (PDL) program prior authorizations (PA's) requested, approved, and denied are listed in Table 5 below. In order to give two different perspectives on the PA's requested for non-preferred drugs, both calendar year and federal fiscal year summary figures along with partial year data are listed in Table 5.

The percentage of prior authorizations (PA's) for non-preferred drugs that were approved slightly decreased from 99.5% (between August 2002 to December 2002 when the PDL program first began) to its lowest point of 97.0% in calendar year 2003. The percentage of approved PA's for non-preferred drugs increased from it lowest point in calendar year 2003 (97.0%) through calendar year 2004 (97.7%) and continued to increase into calendar year 2005 (98.9%).

The percentage of prior authorizations (PA's) for non-preferred drugs that were denied slightly increased over the life of the PDL Program from 0.5% denied (between August 2002 to December 2002 when the PDL program first began), then peaked at 1.7% denied in calendar year 2004, then decreased slightly to 0.9% denied by calendar year 2005.

Table 5. Preferred Drug List Prior Authorizations

Time Period	Average # Utilizers per Month	Total All PA's Requested	Approved	% pprove	# Approved PUPM*	Denied	% Denied	# Suspended	% Suspende
FFY 2003 (Oct 1, 2002 to Sep 30, 2003)	204,840	80,950	79,200	97.8%	0.0322	193	0.2%	1,557	1.9%
FFY 2004 (Oct 1, 2003 to Sep 30, 2004)	208,995	75,705	73,681	97.3%	0.0294	1,177	1.6%	847	1.1%
Oct 1, 2004 to Mar 31, 2005 (First 6-months of FFY 2005)	205,982	41,052	40,427	98.5%	0.0327	513	1.2%	112	0.3%
Apr 1, 2005 to Sep 30, 2005 (Last 6-months of FFY 2005)	185,932	30,420	30,072	98.9%	0.0270	312	1.0%	36	0.1%
First 6 months - FFY 2006 (Oct 1, 2005 to Mar 31, 2006) 1ST Half of Year 4 – Report #5	129,790	19,073	18,978	99.5%	0.0244	77	0.4%	18	0.1%
Second 6 months – FFY 2006 (Apr 1, 2006 to Sep 30, 2006) 2nd Half of Year 4 – Report #6	107,783	14,410	14,186	98.4%	0.0219	213	1.5%	11	0.1%
Aug 1, 2002 to Dec 31, 2002	200,054	17,866	17,775	99.5%	0.022	91	0.5%	0	0%
Calendar Year 2003	207,593	73,251	71,053	97.0%	0.029	259	0.4%	1,939	2.6%
Calendar Year 2004	204,754	81,440	79,567	97.7%	0.032	1,352	1.7%	521	0.6%
Calendar Year 2005	174,307	60,129	59,487	98.9%	0.028	546	0.9%	96	0.1%

* Per utilizer per month (PUPM)

5. Impact of the PDL Upon Recipient's Access to Medications

Recipients affected by the PDL program would be those taking a non-preferred medication before PDL implementation. Affected recipients would then either have:

- switched to a preferred medication;
- received a prior authorization to continue with their non-preferred medication;
- switched to a preferred medication for a short period then switched back to a non-preferred medication, or
- stopped taking their medication (either due to experiencing a denied claim at the pharmacy or, due to the fact that the medication was no longer needed).
- or, dropped out of the analysis because they were no longer eligible and no longer received medications through the Medicaid program.

Recipients were tracked after each denied claim for a non-preferred medication to evaluate whether the denied claim was followed by a paid claim within 30 days of the denial. Then for Reports #4, #5, and #6, recipients were additionally followed from 30 to 180 days after the denial as well as within the first 30 days of denial.

Report #1 Evaluation

In Report #1, 23 classes contained enough claims data 12 months after PDL implementation to assess the PDL program's impact on users' access to medications. Of the 188,508 monthly recipients followed 12 months after the initial PDL program began, only 1,485 (0.78%) experienced a denied claim with no paid claim for a related medication within 30 days. It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies.

Report #2 Evaluation

See Adherence Study on page 31.

Report #3 Evaluation

In Report #3, the PDL program's impact on users' access to medications after the PDL program had been operating for a long time period was assessed. Retail pharmacy prescription claims were examined at 26 and 31 months after initial implementation. Of the 203,463 monthly recipients followed for 26-months after, and of the 208,693 monthly recipients followed for 31-months after the initial PDL program began, only 3,288 (1.5%) experienced a denied claim in the two months of October 2004 and March 2005.

A random sample of 1,000 retail pharmacy Medicaid recipients' claims were analyzed during the month of October 2004 after the recipient experienced a denied claim due to a non-PDL prescription claim. Another random sample of 750 was analyzed in the month of March 2005. Of the 1,750 recipients followed from the initial claim rejection due to a non-PDL prescription claim, only 47 recipients (0.023%) in October 2004 and 28 recipients (0.013%) in March 2005 experienced a denied claim with no paid claim for a related medication within the next 30 days.

Report #4 Evaluation

Medicaid recipients' claims during the month of September 2005 were evaluated for Report #4. Analysis focused on two therapeutic classes of maintenance medications – both antihypertensive drugs – angiotensin converting enzyme Inhibitors (ACE Inhibitors) and angiotensin receptor blockers (ARBs). Only 107 recipients experienced a claim rejection due to a non-PDL ACE Inhibitor prescription claim, and 194 recipients experienced a claim rejection due to a non-PDL ARB. Of the 107 recipients who experienced a claim rejection due to non-PDL ACE Inhibitors, only two recipients experienced a denied claim with no paid claim for a related medication within the next 30 days. Of the 194 recipients who experienced a claim rejection due to non-PDL ARBs, only two recipients (1.03%) experienced a denied claim with no paid claim for a related medication within the next 30 to 180 days.

It is impossible, with such a small sample of two within each therapeutic class, to conclude whether these recipients were simply aberrations and no longer needed the antihypertensive medication, or whether the two recipients' access to care was really impaired. Both recipients received medications for other problems after experiencing a denied claim for a non-PDL ACE inhibitor. So, it would seem plausible that these recipients still had access to care for antihypertensive as well as other treatments and were possibly were not adherent with their antihypertensive therapy or no longer needed the antihypertensive drug.

Report #5 Evaluation

Medicaid recipients' claims were evaluated during the month of January 2006 for 15 therapeutic classes of maintenance medications. Of the 15 therapeutic classes in the month of January 2006, a total of 27,656 unique recipients had paid and denied claims. For January 2006, 27,398 recipients (99.1%) had paid claims and only 258 recipients (0.9%) experienced a denial. Twenty-six of the 258 recipients experienced a denied claim with no subsequent paid claim because they were no longer eligible. Of 232 (0.84% of 27,656) recipients still eligible and who experienced a denied claim, 35 (0.13%) recipients did not have a subsequent paid claim and 197 (0.71%) recipients had a subsequent paid claim. Of the 197 recipients (who had a subsequent paid claim, 163 (83% of 197 and 0.59% of total recipients) received a paid claim within 24 hours to 30 days after the PDL exception denial hit. Over 95% of the 163 recipients who had

exceptions with subsequent paid claims were getting early fills of medication; therefore, if recipients received the medication within 30 days of the PDL exception, there should be no break or discontinuance in therapy due to lack of access to medications. Of the 197 recipients who experienced a PDL exception (denial) and who had a subsequent paid claim, 34 (17% of 197 and 0.12% of total recipients) received a paid claim within 31 to 180 days of the denial.

The 34 (0.12%) recipients who experienced a denial with a subsequent paid claim 31 to 180 days later may have experienced a delay in taking medication. There is also possibility that some of these recipients had samples or other medications at home and therefore did not request the medication again until they needed it. Of the 35 (0.13%) recipients who did not have a subsequent paid claim, it is impossible to determine how many may have gotten their medications through the Medicare D program and how many may no longer have needed the maintenance medication.

Overall, the initial number of recipients who may have experienced a delay in receiving needed medications (0.78% without a related claim within 30 days of the denial in the first year) suggests a minimum impact on PDL users. Further, denials diminished monthly as providers gained experience with the program as evidenced by the 0.023% at 26 months and 0.013% at 31 months after the program began.

Finally, in January 2006 even with the confusion of Medicare D implementation, the number of Medicaid recipients who may have experienced a delay in receiving medications (0.12% without a related claim within 30 days of the denial and 0.13% without a related Medicaid paid claim for a total of 0.25%) suggests a minimum impact on PDL users.

Adherence Study (Report #2 Evaluation)

It is impossible to know from pharmacy administrative claims data what portion of dropped claims were duplicate or unnecessary therapies. Dropped claims are defined as recipients experiencing a denied claim for a non-PDL drug and received no other drug within 30 to 180 days afterward. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. Claims data does not allow full explanation for the therapy interruptions. For example, there are many potential reasons other than PDL such as: physician sampling of medications, other 3rd party liability, patient adherence, or changes in patient therapy.

To put this into perspective, the rate of non-preferred claims denials where recipients had no later related claim within the next 30-days is far lower than the 30 to 50% non-adherence rate after receiving medications documented in the literature. Since between 30 to 50% of all patients fail to follow their prescribed therapy once they receive it, non-adherence or lack of persistence with taking medications may be a larger concern. Therefore, analysis in Report #2 examined recipients who were non-adherent (as

evidenced by inconsistent prescription claims history) with their medications after receiving non-preferred and preferred medications.

KEY OBSERVATIONS:

Recipients who were persistent in taking their medications had significantly lower mean expenditures for physician office visits, emergency room visits, and laboratory procedures than recipients who were non-adherent. The results illustrate that the problem with recipients' health outcomes for Indiana recipients are less likely to be related to whether recipients are taking non-preferred or preferred medications, but rather are more likely to be related to whether recipients will be adherent with taking any prescribed medication, whether it is preferred or non-preferred.

Access to Care Results

1. The proportion of users with an exception event (a denied claim due to PDL program) was extremely low.

2. Recipient ineligibility explains why some exception events did not result in a prescription being filled for a medication in the class or a related class.

3. "Delays" in the receipt of medications were in part due to recipients seeking to refill their prescriptions too early.

4. Relatively few eligible recipients with an exception event had no claims for follow up medication in the same or a related class within 30 days of the event.

Overall, the initial number of recipients who may have experienced a delay in receiving needed medications (0.78% without a related claim within 30 days of the denial in the first year) suggests a minimum impact on PDL users. Further, denials diminished in later evaluation periods as providers gained experience with the PDL program as evidenced by the 0.023% at 26 months, 0.013% at 31 months, and 0.05% at 49 months after the program began.

Conclusions

All analyses have shown that the PDL program has not created any significant barriers to medically necessary medications. Since the beginning of the first analysis report, there has been no evidence found to suggest that access to care is being compromised or that quality of care for recipients has suffered as a result of the PDL program. In fact, adherence was demonstrated to be the more significant issue, not whether recipients were taking a preferred or non-preferred medication.

6. Impact of PDL upon Medicaid Recipients' Medical Costs

OMPP required ACS Government Healthcare Solutions to conduct a study to analyze the Indiana preferred drug list program (PDL) to determine if the PDL results in a negative impact on the health outcomes of Medicaid recipients as well as any cost shifting to other health care providers, laboratory, emergency or hospital services.

Methods

This study used retrospective, paid claims data to evaluate recipient outcomes that may be related to implementation of the PDL program. Any changes in medical utilization or costs for those affected by the PDL program, relative to those not affected, would be *indicators of a possible association* between the PDL program and health outcomes.

It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned to take preferred or non-preferred drugs; therefore, only association or lack of association can be determined. Sample sizes were measured in number of recipients.

Data

The data for this study were derived from the historical paid claims files from the Indiana Medicaid program. Medical data extracts were created and stored on ACS Government Healthcare Solutions data warehouse for the period of March 1, 2002 to September 30, 2006.

Medical Data Study Period

Analyses of the effects of PDL implementation on medical utilization and costs was limited to certain therapeutic groups where potential changes were most likely to have occurred as a result of PDL implementation. Study period one was 6-months prior to and 6-months after each specific therapeutic class' PDL implementation. The month of implementation was excluded in the medical analyses since most implementations occurred mid-month. Study period two was 12-months post- to two years post-implementation. Study period three was 26 to 31 months post-implementation (10/1/04 to 3/31/05). Study period four was 32 to 37 months post-implementation (4/1/05 to 9/30/05). Study period five was 38 to 43 months post-implementation (10/1/05 to 3/31/06). Study period six was 44 to 49 months post-implementation (4/1/06 to 9/30/06).

Outcome Measures

Selected outcomes measures studied were expenditures for physician office visits, emergency room services, laboratory services, number of inpatient hospital admissions and number of inpatient days stayed when hospitalized or institutionalized, as well as total medical expenditures per recipient. Medical outcomes were evaluated 6 months before and for periods of 12, 25, 31, 37, 43 and 49

months after implementation for each of the cohorts or groups of recipients per therapeutic class studied. The initial month of PDL implementation for the associated therapeutic class was assigned a null period in which no measurements were taken.

Outcome Measure Definitions

Physician office visits were defined by detailed procedure codes associated with outpatient or office services involving physician evaluation and management of patients. Emergency services were defined by locating the emergency physician services using procedure codes 99281-99288, and then rolling up the costs of all detail numbers associated with those emergency services claims.

Only services related to the disease states treated with the therapeutic class being studied were used in calculating medical expenditures for each service type. This allows a more detailed, narrow scope of expenditures, ensuring that only the expenditures associated with changes in therapy are being included. .

Inpatient hospital services were measured as a count of each admission date per recipient ID and all expenditures associated with each unique recipient ID per admission date on the inpatient UB-92 claims. Inpatient hospital expenditures were measured only for services related to the disease state associated with the therapeutic class being studied.

Cost Definition

To explore the impact of drug use patterns associated with the PDL program on medical costs, Indiana Medicaid claims were partitioned by type of service. The amount actually paid directly by the Indiana Medicaid program minus recipient co-pays and other insurance was used as the Amount Paid for expenditures. We acknowledge that this definition does not capture the full costs of medical expenditures since Medicare is the primary payer for Medicare-covered services and Indiana Medicaid would pay only the balance. However, this study is only measuring differences in paid amounts between two groups. Since we are only interested in payment changes between groups, we contend that amount paid is sufficient because it applies equally to both groups.

Inclusion/Exclusion Criteria

Inclusion/exclusion criteria were applied to all therapeutic classes in the PDL list as shown in Figure 1. After applying the inclusion/exclusion criteria, recipients taking medications from select therapeutic classes were evaluated over a 6-month pre- and a 6-month post-each reporting period.

Figure 1. Inclusion/Exclusion Criteria for Therapeutic Classes Studied in the Medical Analyses

Therapeutic classes chosen for inclusion in studying medical data were:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, recipients taking medications only in therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation medical data for study inclusion in Report #1. These same recipients in the original 8 therapeutic classes (who were still eligible) were subsequently followed-up in the 2nd, 3rd, 4th, and 5th reports, along with additional classes that met the inclusion criteria.
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation. A relatively large market shift was defined as therapeutic classes with 95% or less preferred market share prior to PDL program implementation.
- Therapeutic classes with approved use as long-term maintenance therapy for chronic illnesses. This maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or non-preferred drugs for a long, continuous time period. Long-term maintenance therapy increases the likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

Therapeutic classes excluded from medical data analyses were:

- Therapeutic classes with greater than 95% preferred drug market share prior to the PDL implementation. These classes were excluded due to an insufficient number of recipients who switched from non-preferred to preferred in order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it would be impossible to determine if medical expenditures are associated with taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.
- Therapeutic classes with too few recipients taking the medications. The sample size of each therapeutic class must be large enough to obtain statistical significance ($\alpha = 0.05$ with a medium effect size) with reasonable power (.80).

Results

Of the therapeutic classes evaluated, overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation, or already taking non-preferred prior to and after implementation). In other words, recipients affected by the PDL program were not associated with any statistically significant differences in overall medical expenditures when compared to recipients not affected by the PDL program measured at 43 months after PDL implementation. **This finding is consistent with prior Reports #1 through #5 in demonstrating that recipients affected by the PDL program were not associated with any statistically significant differences in overall medical expenditures when compared to recipients not affected by the PDL program measured at 12, 25, 31, 37, 43 and 49 months after PDL implementation.**

In sum, when examining **specific medical service types** at 12, 25, 31, 37, 43, and 49 months after PDL implementation of a therapeutic class, there is no evidence to suggest that specific medical costs (e.g. other health care providers, lab, emergency room services or hospital services) are higher on a wide, systematic scale for recipients switched to taking preferred drugs or already taking preferred drugs versus recipients taking non-preferred drugs.

Additionally, of the therapeutic classes evaluated, **overall medical expenditures** of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program (already taking preferred drugs prior to and after PDL implementation). It must be noted that we can only determine association, not causality. This report was not a randomized, controlled design since Medicaid patients were not randomly assigned to take preferred or non-preferred drugs; therefore, only association or lack of association can be determined. Sample sizes were measured in number of recipients.

DISCUSSION AND CONCLUSIONS

In response to increases in prescription drug spending and utilization, many public sector pharmacy benefit programs have been developing and implementing a variety of innovative policy solutions for more effective management of pharmacy benefits. One of the methods that several state Medicaid agencies have implemented is the preferred drug list (PDL) program. The concept behind the PDL program is to improve the quality of pharmaceutical care by ensuring that the most clinically appropriate drug is used, while taking into account the relative costs of the available therapeutically equivalent alternatives. PDL programs may be able to address the problems associated with:

- Recipients who rarely see or pay the true costs of their drugs; and therefore have no incentive to choose less expensive, yet equally effective medications.
- Prescribers who lack current knowledge of the true costs of medications being prescribed.

This evaluation demonstrates that a Preferred Drug List program does decrease net drug expenses. The most substantial net savings from federal CMS rebates are realized within the first year of the PDL program when the largest number of recipients shifts from non-preferred drugs to preferred drugs. Furthermore, the market share movement identified through this evaluation suggests that educating prescribers to prescribe and recipients to utilize preferred drugs works. As a result of moving market share to the preferred products, the PDL program produced net savings with both federal and supplemental rebates.

Additionally, after following nearly 38,000 recipients in eight therapeutic classes for 3 ½-years post-PDL implementation, no evidence was uncovered to suggest an association between the PDL and negative impacts on the quality of care or the ability for recipients to obtain medications. Specifically, there is no evidence at 12-months, 2-years (25 months), 2 ½ years (31 months), 3 years (37 months), or 3 ½ years (43 months) post-PDL implementation to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospital services is occurring on a wide, systematic scale.

Finally, since the beginning of the first report to the most current report analyzing the impact of the Indiana PDL program, there has been no evidence found to suggest that access to care is being harmed or that quality of care for recipients has suffered as a result of the PDL program.